OUTREACH:
A COLLABORATIVE EFFORT

Many people's work finds fruition in Outreach

OC

ODE

OHIP

OSB

OSM

OST

PRIMARY AUDIENCES:

- Hospitals
  - Risk Managers
  - Administrators
  - Central Suppliers
  - Infection Control
- Third-Party Reprocessors
- Consumers
  - General
  - Patients (disease specific)
- Internal
  - Center audience
  - Field

OUTREACH EFFORTS

- FDA Proposed Strategy on Reuse of Single-Use Devices (11/1/99)
- FDA Talk Paper: FDA Proposes New Strategy on Reuse of Single-Use Medical Devices (11/1/99)
- FDA Satellite Teleconference: Proposed FDA Strategy for Reuse of Single-Use Medical Devices (11/10/99)
- Article in User Facility Reporting Bulletin: Reuse of Single Use Devices (12/99)
- Open Public Meeting (12/14/99)
  - Executive Summary for Opening Meeting (12/14/99)

OUTREACH EFFORTS (cont'd.)

- Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals: Draft (2/8/00)
- Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme: Draft (2/8/00)
- Web site (Home Page) (6/00)
- Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals: Final (8/14/00)
- Talk Paper: FDA Issues Final Guidance on Reuse of Single-Use Medical Devices (8/2/00)

OUTREACH EFFORTS (cont'd.)

- Article in UFR Bulletin: FDA Releases Final Guidance on Reprocessing and Reuse of Single-Use Devices (8/00)
- Called 49 health professional and trade groups to alert them of Final Guidance
- Sent copy of FDA Talk Paper of August 8 to subscribers
- Sent Reuse Home Page URL to subscribers

OUTREACH EFFORTS (cont'd.)

For Consumers:

- Article in FDA Consumer: Reusing Medical Devices: Ensuring Safety the Second Time Around (Sep/Oct 2000)
- Called 40 consumer organizations about Final Guidance
- Sent letter to 40 consumer organizations to share with their colleagues

TALK CIRCUIT

Partial list of presentations:

- American Society for Healthcare Central Services Professionals (ASHCSP)
- Global Medical Device Conference – Electrophysiology Nurses/CR Board
- Several AAMI Meetings
- Health Industry Group Purchasing Association (HIGPA)
- Association of Professional Infection Control
- Biofilms 2000

TALK CIRCUIT

List of primary CDRH speakers:

- Larry Kessler
- Larry Spears
- Lily Ng
- Barbara Zimmerman
- Karen Stutsman
- Tim Ulatowski
- Don Marlowe
- Katherine Merritt
- Victoria Hitchens
- Stanley Brown
- Terry Woods

REUSE HOME

FDA has re-examined its policy on the issue of reuse of medical devices labeled for single-use. Our primary goal in doing so is to protect the health of the public by assuring that the practice of reprocessing and reusing single-use devices (SUDs) is safe and effective and based on good science.

The public expects and the law requires all medical devices to be safe, effective and manufactured in accordance with good manufacturing practices (GMPs).

FDA has been actively engaged in reuse issues for some time. Our efforts have included research, outreach, inspections, and compliance investigations. In the recent past, we participated in a number of national meetings on this issue, presented an interactive teleconference. held an open public meeting and then published a proposed strategy. Our current guidance, published on August 14, 2000, was based on the information obtained in these public forums and comments received.

The guidance is an approach that equitably applies existing regulations to original equipment manufacturers (OEMs), third parties, and hospitals to minimize risks associated with reprocessed SUDs.

Despite a lack of clear data that directly link injuries to reuse, FDA has concluded that the practice of reprocessing SUDs merits increased regulatory oversight. We are concerned because we do not have enough information to be certain that SUDs are being reprocessed properly. FDA recognizes that our medical device problem reporting systems cannot adequately capture information about potential clinical problems related to reuse. Our plan is to phase-in additional oversight based on assessment of current practice and potential risk.

(updated 9/20/2000)

Available Documents

Consumer Article: "Reusing Medical Devices: Ensuring Safety the Second Time Around" (9-10/2000) - August 18, 2000	Text
GAO Report: Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted (6/20/2000) - August 18, 2000	Text PDF
Article in User Facility Reporting Bulletin: FDA Releases Final Guidance on the Reprocessing and Reuse of Single-Use Devices (8/2000)	PDF
Article in User Facility Reporting Bulletin: Reuse of Single Use Devices (12/1999)	PDF
Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals - August 14, 2000	Text PDF
Appendix A: List of SUDs Know To Be Reprocessed (from: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals) - August 14, 2000	Text PDF
Talk Paper: FDA Issues Final Guidance on Reuse of Single-Use Medical Devices - August 2, 2000	Text
Statement by Dr. David W. Feigal before the Senate to discuss the Agency's approach to the issue of reuse of medical devices labeled for single-use - June 27, 2000	Text
Statement by Dr. David W. Feigal, Director CDRH, Before the Subcommittee on Oversight and Investigations-February 10, 2000	Text
Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (Draft) - February 8, 2000 (superceded by August 2, 2000 document)	Text PDF
Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme (Draft)- February 8,	Text PDF

Frequently Asked Questions

Q *What are some known reprocessed single-use devices (SUDs)?*

A The known reprocessed SUDs are: surgical saw blades; saw blades; surgical cutting accessories; surgical drills; surgical mesh; drill bits; laparoscopy scissors; endoscopic carpal tunnel blades; orthodontic (metal) braces; electophysiology catheters; electrosurgical electrodes and pencils; cardiac catheters and guidewires; respiratory therapy and anesthesia breathing circuits; biopsy needles; endotracheal tubes; syringes; sutures; staplers; balloon angioplasty catheters; biopsy forceps and trocars. *(posted 5/3/00)*

We are presently formulating questions and answers for this page. Look for updates in the near future. If you have a question of general interest that you would like to submit, click on the "Info/Questions" button to send your question.

(Updated 9/19/00)

Standards

Standards may be as useful in premarket submissions for reprocessed single use devices (SUDs), as they are for submissions from original equipment manufacturers. If the standards used have been recognized by FDA, testing data generally do not need to be submitted. A recently released guidance document explains how consensus standards may be used in premarket submissions including those for reprocessing of SUDs. The guidance is available at:

www.fda.gov/cdrh/ode/guidance/1131.html.

The following list contains both recognized standards and standards that have not yet been recognized but which may be useful in the reprocessing of SUDs. We have included links to some of the developers of major device consensus standards to allow the reader to get more information about the standards on the list. FDA would like to hear from the public about other consensus standards thought to be useful for reprocessing SUDs. If you have any comments, please send them to Dr. Melvyn Altman. His electronic mail address is: mra@cdrh.fda.gov

Sterility and Cleaning Standards and Related Documents for Medical Devices

Researched by Center for Devices and Radiological Health (CDRH)
Office of Science and Technology (OST)
Updated: July 7, 2000

Association for the Advancement of Medical Instrumentation (AAMI)
1110 N. Glebe Road, #220
Arlington, VA 22201-5762
Telephone: 703-525-4890, 1-800-332-2264
Fax: 703-276-0793
Website: www.aami.org

- Vol 1.1: Sterilization Part 1: Good Hospital Practice *(posted*

Events

Upcoming Events

Past Events

Presentations | Teleconferences | Open Public Meetings

Presentations

October 13, 2000
Southern Florida Materials Managers Association
Pompano Beach, Florida
Scheduled FDA Speaker: Larry Kessler
EMail: pdolan@nbhd.org

October 26, 2000
Waste Management Institute
Alexandria, Virginia (Hilton Hotel)
Scheduled FDA Speaker: Diane Goldsberry

October 30, 2000
AAMI/FDA Reprocessing of Single-Use Devices: New FDA Requirements for Hospitals
Shady Grove Center - University of Maryland University College
Rockville, Maryland
Scheduled FDA Speakers: Larry Spears, Tim Ulatowski, Barbara Zimmerman, Karen Stutsman, Al Thomas
Organization: http://www.aami.org/meetings

November 2-5, 2000
American Society of Healthcare Risk Management
New Orleans, LA
Scheduled FDA Speaker: Lily Ng
Organization: http://www.ashrm.org

November 6, 2000
International Association of Healthcare Central Services Material Managers (IAHCSMM)
Birmingham, AL
Scheduled FDA Speaker: Larry Spears
EMail: mailbox@iahcsmm.com

U.S. Food and Drug Administration - Center for Devices and Radiological Health

Reuse of Single Use Devices

REUSE HOME
Documents
FAQs
Standards
Events
Info/Questions

To receive the latest information on the reprocessing and reuse of SUDs, sign up for the Reuse Mailing List.

Please enter your complete email address and then select subscribe or unsubscribe to our **electronic mailing list.**

Your email address:

Subscribe | Unsubscribe | Clear

Subscribe or unsubscribe to other CDRH mailing lists

Note: These email address are considered confidential and will not be released

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To e-mail a question to FDA, please complete the form below.

(required fields are marked with a red star*)

(*) Name:
Title:
Organization:
(*) Address:
City: **State:**
Zip:
(*) Phone:
Fax:
E-mail:
(*) Question:

REUSE HOME PAGE

http://www.fda.gov/cdrh/reuse/index.shtml

E-MAIL ADDRESS

reuse@cdrh.fda.gov

REUSE IN PROGRESS

- Brochure
- Reuse packet
  - Overview letter from Dr. Feigal & copy of August 14 Guidance mailed to 6100 hospitals (labels courtesy of AHA) & US Government hospitals
- CD-ROM
  - Short segments on regulatory requirements
  - Distribution plan needed
- Contracts
  - JCAHO survey
  - AAMI to train inspectors in Quality System Regulation

IN PROGRESS (cont'd.)

- Consumer articles
- Workshops (1 or 2) for 3rd party reprocessors
- Satellite teleconference (12/13/00)

FUTURE PLANS

- Contract to develop curriculum for training
- Investigate infomercials on health networks

WHAT ARE YOUR NEEDS?

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WHAT ARE YOU DOING TO SPREAD THE WORD?

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